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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,874	11/09/2001	John C.K. Hui	4857-00001/CPG	6093
27572	7590	07/27/2004	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			THANH, QUANG D	
			ART UNIT	PAPER NUMBER
			3764	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/037,874	Applicant(s) HUI, JOHN C.K.	
	Examiner Quang D. Thanh	Art Unit 3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-80 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/21/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/21/2004 has been entered.

2. This office action is responsive to the amendment filed on 06/21/2004. As directed by the amendment, claims 1-42 were cancelled and new claims 43-80 were added. Thus, claims 43-80 are presently pending in this application.

Claim Objections

3. Claim 43 is objected to because of the following informalities: "said inflatable devices" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "said computing device" is unclear to what computing device (local or remote computing device?) and "a

Art Unit: 3764

second computing device” is unclear whether this is another additional computing device or is the same as the remote computing device already recited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 43-49, 50-74, and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng et al. (5,997,540) in view of Shabty et al. (6,450,981 B1) and Stark et al. (6,371,123).

7. Re claims 43, 50-52, and 61-62, Zheng et al. discloses a counterpulsation system (fig. 1) comprising: a counterpulsation device having a plurality of inflatable devices 25, a source of compressed fluid 20, a fluid distribution assembly 21/22/24 (fig. 1); a sensor operable to sense diastolic and systolic blood pressure data (col. 5, lines 16-56); a local computer 7 in communication with the fluid distribution assembly of the counterpulsation device to obtain data for controlling the operation of the counterpulsation device, receiving said diastolic and systolic blood pressure data, generating a blood pressure waveform (col. 11, lines 7-19), operable to control said fluid distribution assembly by controlling the inflation and deflation of said inflatable device to maximize a ratio of an area under a diastolic portion of said blood pressure waveform to an area under a systolic portion of said blood pressure waveform during counterpulsation

Art Unit: 3764

(col. 6, lines 20-23), except it is silent regarding a data structure for receiving/storing treatment patient information and a remote computing device to receive the patient information over a communication link. However, Shabty teaches a counterpulsation system (fig. 1) comprising a counterpulsation device having a plurality of inflatable devices 22/24/26 (fig. 1); a data structure 126 for storing treatment patient information for one or more patients (col. 2, lines 26-30 and col. 9, lines 44-48); a computer 10 connected to the counterpulsation device for controlling the operation of the counterpulsation device through each inflation/deflation cycle (col. 9, lines 58-62) and also for receiving the treatment information (col. 9, lines 6-62). Additionally, Stark teaches a medical device comprising a local handheld computer 20 having a data structure that can store the patient monitoring results (step 3 in fig. 1, col. 7, lines 15-18), which then communicates with another remote central computer 16 over the telephone line through modem connections (Internet) for further processing of the patient data (step 5 in fig. 1, col. 7, lines 32-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify Zheng's system, to have the computer included a data structure to store treatment patient information for one or more patients, as suggested and taught by Shabty et al. and Stark et al., for the purpose of providing and updating a patient profile database that can be used to determine the effectiveness of a counterpulsation therapy regime for an individual patient or selected study groups (Shabty, col. 10, lines 1-4), and to have the system included another remote central computer, as suggested and taught by Stark et al., for the purpose of communicating patient

Art Unit: 3764

information over the Internet in order to allow review by a treatment professional or to allow updating patient database (Stark, col. 7, lines 50-66).

8. Re claims 44-49, 53-57, 63-67, 72-74 and 80, Shabty further discloses that the data structure is for storing demographic information including patient ID, name and medical data and for storing treatment information including ECG (EKG), blood pressure, heart rate (col. 6, line 60 to col. 7, line 45), and inflation/deflation timing data (col. 7, lines 33-37).

9. Re claim 71, Shabty discloses a counterpulsation system (fig. 1) comprising: a counterpulsation device having a plurality of inflatable devices 22/24/26 and inflation/deflation valve 18 (fig. 1); a data structure 126 for storing treatment patient information for one or more patients (col. 2, lines 26-30 and col. 9, lines 44-48); a computer 10 connected to the counterpulsation device for controlling the operation of the counterpulsation device through each inflation/deflation cycle (col. 9, lines 58-62), for receiving the treatment information (col. 9, lines 6-62), and outputting the operation information; and an output device (display screen) connected to the local computer for displaying treatment and operation information (col. 6, lines 11-20).

10. Re claims 58-60, and 68-70 Stark teaches that the remote central computer having a database 26 is a medical registry computer (col. 8, lines 33-58), is a computer operable for remote diagnosis (col. 9, lines 16-21), and is a computer operable for training (col. 7, line 66 to col.8, lines 3).

Art Unit: 3764

11. Claims 75-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng/ Shabty/Stark in and further in view of Dillon (5,514,079).

12. Zheng/ Shabty/Stark discloses a counterpulsation system having all the claimed features except that it does not explicitly reveal timing bar having leading edge corresponding to the initiation of inflation and trailing edge corresponding to the initiation of deflation, trigger signal, timing marker with high frequency noise superimposed on an ECG in relation to QRS wave. However, Zheng discloses a counterpulsation system having a computer that display the wave form, detects the QRS wave of the ECG, performs adaptive processing of the impedance blood flow signals, measures the waveform's characteristic points and controls the inflation and deflation time of the counterpulsation apparatus (col. 11, lines 11-19). Additionally, Shabty teaches that the counterpulsation therapy is carried out by timing the inflation and deflation of the treatment cuffs with certain characteristics of the patient's EKG signal and the plethysmographic blood pressure wave (col. 7, lines 33-36), and those skilled in the medical therapy art will be able to determining the timing of the inflation and deflation of the treatment cuffs and the coordination of that with the patient's natural blood flow in order to provide the desired therapy effect (col. 8, lines 56-60). Moreover, Dillon teaches that, in order to regulate the timing of compression and decompression such that compression and decompression of a patient's leg is phased to the patient's heart beat, one would need EKG sensing device for monitoring the patient's heartbeat, a computer and a timer (col. 6, lines 12-19). Dillon also teaches that compression and decompression of the patient's leg is regulated by sensing the

Art Unit: 3764

QRS complex in the heart cycle, computing an average time period between a selected number of successive QRS complexes, and initiating a timing cycle for the therapy (col. 4, lines 30-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the system in the combined reference, as suggested and taught by Zheng, Shabty and Dillon, to include means for measuring inflation and deflation time of the counterpulsation apparatus including timing bar having leading edge corresponding to the initiation of inflation and trailing edge corresponding to the initiation of deflation, trigger signal, timing marker with high frequency noise superimposed on an ECG in relation to QRS wave, for the purpose of determining the timing of the inflation and deflation of the treatment cuffs and regulating the timing of compression and decompression such that compression and decompression of a patient's extremity is in coordination of that with the patient's natural blood flow in order to provide the desired therapy effect (Shabty, col. 8, lines 56-60).

Conclusion

13. This is a RCE of applicant's earlier Application No. 10/037,874. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3764

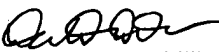
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday-Thursday & alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and After-Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Quang D. Thanh
Patent Examiner
Art Unit 3764
July 26, 2004



Danton D. DeMille
Primary Examiner